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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/589,122	08/10/2006	Barry Peter Liversidge	1926-00120	5703

26753 7590 07/14/2009

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EXAMINER	
PATEL, SHEFALI DILIP	
ART UNIT	**PAPER NUMBER**
3767	

MAIL DATE	DELIVERY MODE
07/14/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/589,122	LIVERSIDGE, BARRY PETER	
	Examiner	Art Unit	
	SHEFALI D. PATEL	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 March 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgments

1. In the reply, filed on March 31, 2009, Applicant amended claims 4, 6-9, and 11-20 as noted by the Examiner in the Notice of Non-Compliant Amendment of March 23, 2009.

2. Currently, claims 1-32 are under examination.

Response to Arguments

3. Applicant's arguments, see pages 10-13, filed on March 31, 2009, with respect to the rejection(s) of claim(s) 1-32 under Jangula (US 2005/0171484) and Sempere (EP 0409180) and/ore other references have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Rand et al (US 5,137,516) and Sempere and/or other references below.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-9, 11-14, 16-19, 21-24, 26-28, 30, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rand et al (US 5,137,516), and further in view of Sempere (EP 0409180).

In regards to claims 1-9, 11-14, 16, and 18, Rand et al teaches a handling device (Figures 17-24, second cap [132]) for use with a medical injector (syringe [16] with sleeve assembly [23]) having a cylindrical body (barrel [17]) provided with a boss at the forward end thereof supporting a forwardly-projecting needle (needle [19]) furnished with a protective sheath (septum [20]), which device [132] comprises:

a. a carrier [132] having an outer cylindrical wall and co-axial therewith an inner tube (cylindrical protrusion [137]) which is a close sliding fit over the protective sheath [20] of a needle [19] (Figures 23-24)

b. a plug (end cap [132a]) slidably mounted on the carrier [132] and projectable from the forward end thereof, the forward end of the protective sheath [20] of a received injector [16][23] engaging the plug (Figures 19-23)

Rand et al does not teach a cylindrical sleeve slidably mounted within the outer cylindrical wall of the carrier, a bushing slidably located within the cylindrical sleeve, and a spring means urging the bushing towards the rear end of the sleeve. Sempere teaches a handling device (Figures 1-3) comprising a carrier (cover [9]), a cylindrical sleeve (sliding body [2]) slidably mounted within the outer cylindrical wall of the carrier, a bushing (body [1]) slidably located within the cylindrical sleeve, and a spring means (spring [8]) urging the bushing towards the rear end of the sleeve (column 2, lines 49-54). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the handling device, of Rand et al, with a sleeve, bushing, and spring means, as taught by Sempere, as the sleeve, bushing, and spring means will provide a protection of the needle by enclosing the needle automatically in the sleeve and bushing after one use, thus ensuring that the used, contaminated needle is no longer usable

for subsequent applications (column 1, lines 7-12). *From Applicant's specification (page 8, line 15), the spring means is performed by a helical compression spring [29].*

In regards to claim 17, in a modified device of Rand et al and Sempere, Rand et al is silent about whether the plug [132a] is of a contrasting color to that of the carrier [132]. However, at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the plug with a contrasting color to that of the carrier because Applicant has not disclosed that contrasting colors provide an advantage, are used for a particular purpose, or solve a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the plug and the carrier being the same color because regardless of color, the plug will still perform the function of closing the open forward end of the handling device. Therefore, it would have been an obvious matter of design choice to modify the plug, of Rand et al, to have a contrasting color to that of the carrier, in a modified device of Rand et al and Sempere, to obtain the invention as specified in claim 17.

In regards to claim 19, Rand et al teaches a medical injector (Figures 17-24, syringe [16] with sleeve assembly [23]) having a cylindrical body (barrel [17]) provided with a boss at the forward end thereof for supporting a forwardly-projecting needle (needle [19]) furnished with a protective sheath (septum [20]). Together Rand et al and Sempere teach a combination of the medical injector and a handling device, as claimed in claim 1 (*see rejection of claim 1 above*).

In regards to claim 21-24, 26-28, and 30, Rand et al teaches a handling device (Figures 17-24, second cap [132]) for use with a medical injector (syringe [16] with sleeve assembly [23])

having a cylindrical body (barrel [17]) provided with a boss at the forward end thereof supporting a forwardly-projecting needle (needle [19]) furnished with a protective sheath (septum [20]), which device [132] comprises:

a. a carrier [132] having an outer cylindrical wall and co-axial therewith an inner tube (cylindrical protrusion [137]) which is a close sliding fit over the protective sheath [20] of a needle [19] (Figures 23-24)

Rand et al does not teach a cylindrical sleeve slidably mounted within the outer cylindrical wall of the carrier, a bushing slidably located within the cylindrical sleeve, and a spring means urging the bushing towards the rear end of the sleeve. Sempere teaches a handling device (Figures 1-3) comprising a carrier (cover [9]), a cylindrical sleeve (sliding body [2]) slidably mounted within the outer cylindrical wall of the carrier, a bushing (body [1]) slidably located within the cylindrical sleeve, and a spring means (spring [8]) urging the bushing towards the rear end of the sleeve (column 2, lines 49-54). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the handling device, of Rand et al, with a sleeve, bushing, and spring means, as taught by Sempere, as the sleeve, bushing, and spring means will provide a protection of the needle by enclosing the needle automatically in the sleeve and bushing after one use, thus ensuring that the used, contaminated needle is no longer usable for subsequent applications (column 1, lines 7-12). *From Applicant's specification (page 8, line 15), the spring means is performed by a helical compression spring [29].*

In regards to claim 31, Rand et al teaches a medical injector (Figures 17-24, syringe [16] with sleeve assembly [23]) having a cylindrical body (barrel [17]) provided with a boss at the forward end thereof for supporting a forwardly-projecting needle (needle [19]) furnished with a

protective sheath (septum [20]). Together Rand et al and Sempere teach a combination of the medical injector and a handling device, as claimed in claim 1 (*see rejection of claim 21 above*).

6. Claims 10 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rand et al and Sempere, as applied to claims 9 and 24 above, and further in view of Jangula (US 2005/0171484).

In regards to claims 10 and 25, in a modified device of Rand et al and Sempere, Sempere does not teach that the rear end of the sleeve [2] has radially-inwardly directed nibs with which the bushing [1] is engageable. Jangula teaches a handling device (Figures 2-4) wherein the rear end of a sleeve (bushing [46]) has radially-inwardly directed nibs (inward extending stop surfaces [48]) with which a bushing (cap [30] with adapter [40]) is engageable (Figure 4). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the sleeve, of the modified device of Rand et al and Sempere, with radially-inwardly directed nibs, as taught by Jangula, as the radially-inwardly directed nibs of the sleeve will act as a stop means to control and limit the forward movement of the bushing within the sleeve (paragraphs [0027][0028]).

7. Claims 15, 20, 29, and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rand et al and Sempere, as applied to claims 1 and 21 above, and further in view of Pizzino (US 4,702,737).

In regards to claims 15 and 29, in a modified device of Rand et al and Sempere, Rand et al does not teach that the boss at the forward end of the cylindrical body [17] is externally screw-

threaded, for use with a needle having a hub with an internally-threaded socket co-operable with the threads of the boss. Pizzino teaches an injector (Figure 1, syringe [10]) having a boss (externally screw threaded tubular conduit [46]) with external screw threads that are co-operable with the internal screw threads of a hub (internally screw threaded hub [52]) of a needle [48]. It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the boss and needle hub, of the injector of the modified device of Rand et al and Sempere, with threads, as taught by Pizzino, as such will provide a means for the attachment of a needle to an injector and will provide a means to prevent re-use of a needle as a new needle will be screwed onto the injector for every use of the injector (column 2, lines 63-68 to column 3, lines 1-8).

In regards to claim 20, with a modified device of Rand et al and Sempere, Rand et al teaches a method of using a handling device [132], as claimed in claim 1, with a medical injector [16][23] having a cylindrical body [17] provided with a boss at the forward end thereof for supporting a needle [19] and a needle sheath [20] surrounding and protecting the needle, comprising the steps of:

a. pushing the carrier [132] on to the forward end of the injector [16][23], the sheath [20] is coupled to the inner tube [137], and the sheath engages the plug [132a] and pushes the plug forwardly to project from the carrier (column 11, lines 8-10)(column 12, lines 52-53)

b. pulling the carrier [132] away from the cylindrical body [17] of the injector [16][23] with the sheath [20] retained within the inner tube [137] (column 12, lines 60-62)

c. pushing the carrier [132] once more on to the forward end of the injector [16][23] to refit the sheath [20] on the needle [19] (column 13, lines 3-5)

Rand et al does not teach pushing a carrier with a sleeve, a bushing, and a spring onto the injector, and pulling the carrier away from the injector to retain the sleeve and the bushing on the injector. Sempere teaches pushing a sleeve [2], a bushing [1], and a spring [8] onto an injector [4] (column 2, lines 25-39). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the method, of the modified device of Rand et al and Sempere, by pushing a sleeve, a bushing, and a spring onto the injector, as taught by Sempere, as the sleeve, bushing, and spring will provide a protection of the needle by enclosing the needle automatically in the sleeve and bushing after one use, thus ensuring that the used, contaminated needle is no longer usable for subsequent applications (column 1, lines 7-12). Further, Rand et al does not teach that the injector [16][23] has an externally threaded boss for supporting the internal threads of a needle hub of a needle. Pizzino teaches an injector (Figure 1, syringe [10]) having a boss (externally screw threaded tubular conduit [46]) with external screw threads that are co-operable with the internal screw threads of a hub (internally screw threaded hub [52]) of a needle [48]. It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the boss and needle hub, of the injector of the modified device of Rand et al and Sempere, with threads, as taught by Pizzino, as such will provide a means for the attachment of a needle to an injector and will provide a means to prevent re-use of a needle as a new needle will be screwed onto the injector for every use of the injector (column 2, lines 63-68 to column 3, lines 1-8).

In regards to claim 32, with a modified device of Rand et al and Sempere, Rand et al teaches a method of using a handling device [132], as claimed in claim 21, with a medical injector [16][23] having a cylindrical body [17] provided with a boss at the forward end thereof for supporting a needle [19] and a needle sheath [20] surrounding and protecting the needle, comprising the steps of:

a. pushing the carrier [132] on to the forward end of the injector [16][23], the sheath [20] is coupled to the inner tube [137] (column 11, lines 8-10)(column 12, lines 52-53)

b. pulling the carrier [132] away from the cylindrical body [17] of the injector [16][23] with the sheath [20] retained within the inner tube [137] (column 12, lines 60-62)

c. pushing the carrier [132] once more on to the forward end of the injector [16][23] to refit the sheath [20] on the needle [19] (column 13, lines 3-5)

Rand et al does not teach pushing a carrier with a sleeve, a bushing, and a spring onto the injector, and pulling the carrier away from the injector to retain the sleeve and the bushing on the injector. Sempere teaches pushing a sleeve [2], a bushing [1], and a spring [8] onto an injector [4] (column 2, lines 25-39). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the method, of the modified device of Rand et al and Sempere, by pushing a sleeve, a bushing, and a spring onto the injector, as taught by Sempere, as the sleeve, bushing, and spring will provide a protection of the needle by enclosing the needle automatically in the sleeve and bushing after one use, thus ensuring that the used, contaminated needle is no longer usable for subsequent applications (column 1, lines 7-12). Further, Rand et al does not teach that the injector [16][23] has an externally threaded boss for

supporting the internal threads of a needle hub of a needle. Pizzino teaches an injector (Figure 1, syringe [10]) having a boss (externally screw threaded tubular conduit [46]) with external screw threads that are co-operable with the internal screw threads of a hub (internally screw threaded hub [52]) of a needle [48]. It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the boss and needle hub, of the injector of the modified device of Rand et al and Sempere, with threads, as taught by Pizzino, as such will provide a means for the attachment of a needle to an injector and will provide a means to prevent re-use of a needle as a new needle will be screwed onto the injector for every use of the injector (column 2, lines 63-68 to column 3, lines 1-8).

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Brunnberg et al (US 2006/0100588), Ejlersen et al (US 4,976,701), McFarland (US 4,772,272), Marshall (US 5,928,205), Wyrick (US 2006/0173408), and Ott et al (US 5,436,994).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHEFALI D. PATEL whose telephone number is (571) 270-3645. The examiner can normally be reached on Monday through Thursday from 8am-5pm Eastern time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin C. Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shefali D Patel/
Examiner, Art Unit 3767
07/12/2009
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